Efficacy Review

Date: November 4, 2010

Efficacy Reviewer: Clayton Myers, Ph.D., Entomologist, RD-IB
myers.clayton@epa.gov
703-347-8874

11/4/10

Risk Manager Rev.: BeWanda Alexander

Products: Ortho Home Defense Indoor and Outdoor Insect Killer

EPA Reg. #: 239-2695

A.I.'s: Bifenthrin (0.05%), Prallethrin (0.03%)

Decision #s: 435803

DP #s: 382603

Submission: R340, Amendment, Non-fast-track, RD Science Review
(cite-all for other claims)

MRIDs: Cited: 45060601, 46371601, 46393501, 46553201, 46888508, 47086001, 47311109, 47425001, 47711501, 47711502, 47711503, 47711504, 48103101, 48103102, 48103103

GLP: No

MRID 45060601 Studies were previously reviewed by Mark Suarez (5 August 2008), and data were found to be adequate to support kills claims against Hobo spiders.

MRID 46371601 Studies were previously reviewed by Clayton Myers (31 July, 2009) and were found to be insufficient to support any outdoor residual efficacy claims against cockroaches—the exposures were forced for 60 minutes and only indoor surfaces were evaluated.

MRID 46553201 Studies were reviewed by Mark Suarez (2 November, 2005) and were deemed inadequate to support controls claims for any pests of public health concern, per a prior review and required corroborative data submission under a conditional registration for the product supported by this study. This submission is superseded by MRID 47711502.

MRID 46393501 Studies were previously reviewed by Mark Suarez (5 April 2005) and were determined to be insufficient to support outdoor residual efficacy claims against fleas.

MRID 46888508 The study supports claims for a number of pests that do not require submission of efficacy data, including crickets, earwigs, millipedes, etc.

MRID 47086001 Studies were previously reviewed by Mark Suarez (14 June 2007) and were determined to be insufficient to support outdoor residual efficacy claims against spiders, flies, fleas, or cockroaches at the rates proposed on the product label (and thus this product as well).

MRID 47311109

Title: Evaluation of Residual Efficacy of Ortho Home Defense Indoor & Outdoor Insect Killer (EPA Reg. No. 239-2663)

Guideline: OPPTS 810.3500

Materials and Methods: Studies were conducted in the laboratory with forced exposure of a number of species of ants and scorpions (Western Harvester Ants, Carpenter Ants, Red Imported Fire Ants, Stripe Tail Scorpions, and Dune scorpions). Arthropods were exposed for 24-96 hours to 2 surfaces (linoleum tile, and plastic) treated with bifenthrin and aged from 416-541 days in the laboratory. Four replicates of each surface were used for each pest species, with various numbers of pest per replicate. Mortality assessments were conducted at 24, 48, 72, and 96 hours after introductions. Percent control was calculated using Abbott's formula in comparison to mortality on untreated controls.

Study Summary of the Results:

1. Control of all ant and scorpion species was greater than 90% on surfaces aged from 416-541 days after treatment.

Entomologist's Observations/Discussion:

Because the forced exposure durations were too long (24 hours) and far exceed what would normally be encountered under typical use conditions, these data alone are inadequate to support a standard residual claim for ants or scorpions. Because there is confusion over the adequacy of existing and past performance standards for these claims, the Agency may require registrants to submit further data in the future with regard to residual control claims for scorpions, and other pests, demonstrating efficacy under more realistic field-like conditions.

MRID 47425001 Studies were re-reviewed on by Clayton Myers (August 9, 2010). It was determined that forced exposure durations were too long (24 hours) to support a standard residual claim for ants or scorpions. Because there is confusion over the adequacy of existing and past performance standards for these claims, the Agency may require registrants to submit further data in the future with regard to residual control claims for scorpions, and other pests, demonstrating efficacy under more realistic field-like conditions.

MRID 47711501 Studies were previously reviewed by Clayton Myers (August 26, 2009). Mean knockdown time for cockroaches was 21.22 seconds, within a SD of 11.84 seconds. 100% mortality was achieved within 30 minutes of treatment. >90% knockdown was achieved in each treatment. Because this study evaluated a product that included a second active ingredient

(prallethrin) this product supports additional efficacy claims beyond that supported by bifenthrin alone. Knockdown, quick kill claims, etc. are supported for American cockroaches.

MRID 47711502 Studies were previously reviewed by Clayton Myers (August 26, 2009). Residual control from bifenthrin was dependent on the species and exposure time, though all species required less than 60 minutes exposure on non-porous surfaces. Replication for studies with scorpions was inadequate (2 replicates of 1 scorpion in each). Five month control efficacy was adequate for Ants (including Harvester Ants, but excluding Carpenter Ants, Pharaoh's Ants, and Foraging Fire Ants), Carpet Beetles, Crickets, Firebrats, Moths, Silverfish, and Spiders on treated non-porous surfaces after 5 minutes of continuous exposure. Efficacy was adequate for German cockroaches after 30 minutes of continuous exposure. Because there is confusion over the adequacy of existing and past performance standards for these claims, the Agency may require registrants to submit further data in the future with regard to residual control claims for scorpions, and other pests, demonstrating efficacy under more realistic field-like conditions.

MRID 47711503 Studies were previously reviewed by Clayton Myers (August 26, 2009). Migration of ants from the original nest to side nests was prevented for 2 of 3 replicates on bifenthrin treated brick and for all 3 replicates of bifenthrin treated mulch (20 cm x 10 cm). Observations were not taken on ceramic or vinyl. On concrete, worker foraging activity was reduced approximately 80-90% throughout the 6 week study. On mulch, near 100% reduction was achieved from day 14-42, although reduction was less effective prior to day 14. Bifenthrin was only moderately effective in killing queens, workers, and broods (~40% mortality). Bbecause the study was conducted indoors, it is unknown how long this treatment efficacy would last under outdoor conditions, weathering, etc. Therefore an outdoor barrier claim, controls claim, or foraging claim is not supported since no realistic time component can be determined for product efficacy. Additionally, because forager and queen mortality was not adequate, this data does not support a controls claim for Pharaoh Ants.

MRID 47711504 Submission is a peer reviewed journal article regarding application of bifenthrin granules to form barriers against ants. Ant mortality was not assessed and repellence of ants was not shown to meet or exceed the 90% threshold.

MRID 48103101

Title: Twelve month control of indoor crawling arthropods with 0.05% bifenthrin applications on non- and semi-porous surfaces

Guideline: OPPTS 810.3500

Materials and Methods: Studies were submitted evaluating 12 month residual activity of bifenthrin treated surfaces against various species of ants, cockroaches, scorpions, and spiders. Surfaces were treated with a liquid formulation (equivalent to labeled rates of bifenthrin products) and aged in a laboratory environment for 12 months. Forced exposure assays were conducted with arthropods exposed to treated surfaces for various times (5, 10, 15, 30, 60 minutes, 2, 24 hours). After exposure, arthropods were removed to clean containers for

evaluation of mortality. Mortality was compared to controls using Abbott's formula, and means were compared using ANOVA and the Student Newman-Keul's mean separation test.

Study Summary of the Results:

1. Efficacy exceeded 90% for ants (harvester, carpenter, pharaoh's) on all indoor non-porous and semi-porous surfaces.
2. Efficacy exceeded 95% for cockroaches (American, German, and Oriental), but exposure times far exceeded 5 minutes for surfaces other than plastic
3. Efficacy was 100% for spiders (Brown recluse and Black widow), but exposure times were 24 hours for porous wood surfaces.
4. Efficacy was 100% for scorpions (Bark and Striped tail), with forced exposure ranging from 5 minutes to 2 hours.

Entomologist's Observations/Discussion:

1. For Harvester, Carpenter, and Pharoah's ants, efficacy was supported using 5 minutes forced exposure for all indoor non-porous surfaces (with the exception of harvester ants on glass and linoleum, which required 1 hour of exposure). Efficacy on ceramic was adequate with 30 minutes of exposure for harvester ants and 10 minutes of exposure for carpenter ants.
2. For American cockroahes, efficacy was supported using 5 minutes to one hour forced exposure for all indoor non-porous and semi-porous surfaces. For German and Oriental cockroaches, 5 minutes exposure was only adequate for plastic surfaces. For other surfaces, 2-24 hours exposure was required for efficacy. Claims are not supported for German cockroaches on semi-porous surfaces.
3. For Brown recluse and Black widow spiders, efficacy was supported using 5-60 minute exposures for all indoor non-porous and semi-porous surfaces. 24 hour exposure was required to demonstrate efficacy on wood, so claims for non-porous surfaces are not supported.
4. For scorpions (Bark and Striped tail) efficacy was supported using 5-120 minute exposure for all indoor non-porous and semi-porous surfaces.

MRID 48103102

Title: Six month control of outdoor crawling arthropods with 0.05% bifenthrin applications on multiple surfaces.

Guideline: OPPTS 810.3500

Submission: A summary was submitted listing studies to support various outdoor residual efficacy claims (3, 4, and 6 months) for a number of public health pests. A number of the studies were conducted on indoor surfaces, which do not support outdoor claims.

Entomologist's Observations/Discussion:

-MRID 46180801 describes field studies where bifenthrin granules were assessed for control of imported fire ants for up to 12 months. Efficacy was supported through 6 months. Because the rate of application of the granular product is the same as the rates directed for the submitted product, 6 month claims for fire ant control are supported.

-MRID 46809101 describes field studies where bifenthrin granules were assessed for control of imported fire ants for up to 6 months. Efficacy was supported through 5 months. Because the rate of application of the granular product is the same as the rates directed for the submitted product, 5 month claims for fire ant control outdoors are supported.

-MRID 46371601 was previously reviewed by Clayton Myers (31 July, 2009) and was found to be insufficient to support any outdoor residual efficacy claims against cockroaches—the exposures were forced for 60 minutes and only indoor surfaces were evaluated.

-MRID 44891903 was previously reviewed by Clayton Myers (8 December 2009) and was found to be insufficient to support outdoor residual efficacy claims against german cockroaches.

-MRID 47086001 was previously reviewed by Mark Suarez (14 June 2007) and was determined to be insufficient to support outdoor residual efficacy claims against spiders, flies, fleas, or cockroaches at the rates proposed on the product label (and thus this product as well)

-MRID 46393501 was previously reviewed by Mark Suarez (5 April 2005) and was determined to be insufficient to support outdoor residual efficacy claims against fleas.

-MRID 46508101 was previously reviewed by Mark Suarez (15 August 2005). While the submission was determined to be acceptable for supporting kills claims for scorpions, it is not acceptable to support a 3 month outdoor residual control claim.

Outdoor residual control claims are not supported by this cited data for any pests of public health importance, except for imported fire ant control (6 months).

MRID 48103103

Title: Control of arthropod eggs with 0.05% bifenthrin

Guideline: OPPTS 810.3500

Submission: A summary was submitted citing public literature on efficacy of bifenthrin applications to eggs of Asian Lady Beetles, Two-spotted spider mite, and beet armyworm.

Entomologist's Observations/Discussion: Because these pests are not of public health, structural, or quarantine significance, the Agency does not require submission of efficacy data to support this claims.

Overall Review of Label Claims and Directions:

Based upon submitted efficacy data, 12 month indoor residual efficacy claims are supported for:

1. Ants of all species on non-porous and semi-porous surfaces.
2. American cockroaches and Oriental cockroaches on non-porous and semi-porous surfaces.
3. German cockroaches on non-porous surfaces only.
4. Spiders of all species on non-porous and semi-porous surfaces.
5. Scorpions of all species on non-porous and semi-porous surfaces.

-NOTE: No indoor residual claims are supported for porous (i.e., wood) surfaces.
-Direct kills claims are acceptable for any of the above listed pests, for which residual control data was found to be acceptable. However, kills claims are not supported for any pests for which data was never submitted or cited for this chemical (includes cite-all option for similar bifenthrin products).

Based upon cited efficacy data, outdoor residual efficacy claims are only supported for imported fire ants, for 6 months. All other outdoor residual efficacy claims must be removed from the label. Claims against the listed arthropod eggs are not subject to Agency efficacy review and may be retained.

Line by Line Review of Efficacy Claims and Directions for Use

Kills: Ants (including Carpenter, Foraging Fire Ants, Pharaoh, and Harvester), Bedbugs, Bees, Biting Flies, Centipedes, Chiggers, Cockroaches (including American/Palmetto bug/Water bug, Asian (Oriental) and German), Fleas, Hornets/yellow jackets, House fly, Mosquitoes, Scorpions, Spiders (including Black widow, Brown recluse, Hobo, and Wolf), Termites, Wasps/yellow jackets: Claims against Bedbugs are not acceptable and must be removed from the label.

Also Controls Ticks (including ticks that may Transmit Lyme Disease: Unacceptable, as residual control data was not submitted or cited for ticks.

Also Kills Ticks (including ticks that may Transmit Lyme Disease: Acceptable.

"To control Fleas & Ticks [Including ticks that may transmit Lyme Disease]:" Must be changed to "To kill Fleas & Ticks . . . ."

General:

Kills by contact! Acceptable

Residual Control claims:

Kills bugs inside. Keeps bugs out: Acceptable..

Perimeter/bug barrier claims: Acceptable.

Kills and prevents [listed insects] [inside your home] [outside your home]: Acceptable

Keeps [on] killing with residual action, even after you spray, after spray has dried: Acceptable

Use in . . . to keep listed bugs [listed insects] from entering your home, to kill listed bugs [listed insects]: Acceptable

Long-lasting control, Long-lasting insect control, Long-lasting residual control: Acceptable

Kills [two][2] ways [Dual Action]: 1) Kills listed insects fast [by contact] and 2) Keeps killing even after spray has dried: Acceptable

Immediately [quickly] forms [creates] [establishes] a perimeter treatment, a [bug][insect] barrier: "Immediately" is unacceptable, as no data supported immediate efficacy. The remainder of the claim is acceptable.

[Creates] [Establishes] a [bug] [insect] barrier, Create (a) bug barrier(s): Acceptable

Creates a barrier that [will kill] [kills] the bugs you have and prevent[s] new bugs from coming [in] [inside your home] [all season]: Acceptable

Kills the bugs you have and creates a barrier that prevents new bugs from coming inside your home all season: Acceptable.

[New] Barrier Technology keeps bugs out of your home, keeps bugs from coming in, Long lasting Barrier technology: "New" is unacceptable, as the product has been registered for more than 6 months. "Technology" may imply enhanced efficacy, but the decision on this claim is deferred to the RM Reviewer/PM. A simple 'bug barrier' claim would be acceptable.

Guards against bugs so you don't have to, Guards against the bugs you can't (don't) see: Acceptable.

12-Month Claims: Acceptable as listed with any of the 4 proposed footnotes. The Agency may decide in the future to call-in additional product performance data for products with residual claims.

6 Month Claims: These claims are acceptable for spiders with the listed disclaimer.

5 Month Claims: These indoor claims are acceptable as listed. The Agency may decide in the future to call-in additional product performance data for products with residual claims.

4 Month Claims: These claims are acceptable for spiders with the listed disclaimer.

3 Month Claims:

-Outdoor claims against spiders (excluding black widow, brown recluse, hobo), and harvester ants are acceptable. Outdoor claims against roaches/palmetto bugs/ wager bug, scorpions, and fleas are not acceptable and must be removed from the label.

-Indoor claims against Ants (including Western Harvester), German Cockroaches, and Spiders are, as listed, are acceptable with the listed footnoting.

Egg Killing Claims: Acceptable

Knockdown claims: Acceptable

Other claims:

Kills listed home invading insects: Acceptable

Kills ants [and many other listed pets/listed insects!], [and] roaches [and many other listed pests/listed insects!], roaches [and] spiders [and many other listed pests/listed insects!]: Acceptable

Spreading Characteristics: These claims are unacceptable, and must be removed from the label—no data was submitted demonstrating the movement of active ingredient into cracks, crevices, harborage, etc., and efficacy in those areas was not assessed.